PATENT

Case No. 8627/096

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Fred T. Parker Serial No.: 09/815,567 Filed: March 23, 2001 For: INTRODUCER SHEATH	))))))))))	Art Unit: 3751 Examiner: A. Ramana

RULE 1.132 DECLARATION

I, Sathya Kaliyamoorthy, declare as follows:

1. I am over 18 years of age and competent to make this Declaration.

2. I graduated from the Case Western Reserve University in 2003 with a Ph.D. in Mechanical Engineering.

3. Since 2003, I have been employed by ABAQUS, Inc., of West Lafayette, Indiana. The primary business of ABAQUS is sales, support, and for-fee consulting using the ABAQUS computer program. ABAQUS performs Finite Element Analysis ("FEA"). FEA allows engineers to simulate the physical behavior of engineered products using a computer. FEA further allows these engineers to minimize the number of physical prototype tests performed during development of their products. FEA further allows engineers to gain deeper understanding into the physics of their products than can be gained by physical test alone. The ABAQUS program is commonly used in many industries. Particularly in the medical industry, ABAQUS is commonly used to simulate stents, catheters, and other interventional medical devices.

4. Prior to joining ABAQUS, I was employed by the Cleveland Clinic Foundation for a period of one year as a Research Scholar.

5. I was asked by Cook Incorporated, ("Cook") of Bloomington, Indiana, to examine Cook's United States Patent Application Serial No. 09/815,567 ("the '567 application"), and U.S. Patent No. 5,792,124 to Horrigan, et al., ("Horrigan"). The Horrigan patent was represented to me as being the closest prior art reference cited by the Patent Examiner during prosecution of the '567 application. I was asked to design a computer simulation utilizing Finite Element Analysis ("FEA") to compare the kink resistance of a sheath constructed in accordance with the teachings of the Horrigan patent, to the kink resistance of a sheath otherwise similar to the sheath taught in Horrigan but having a coil reinforcement instead of the braid reinforcement disclosed in Horrigan.

6. The basic computer simulation model that I constructed for the FEA analysis was designed to be representative of a sheath taught in Horrigan. Another model was designed to be representative of the sheath taught in Horrigan, except that a coil reinforcement was substituted for the braid reinforcement of the Horrigan sheath. Whenever possible, the dimensions of the sheaths utilized for purposes of our FEA analysis were selected to be within a range specifically recited in Horrigan. When a specific dimension for a feature was not explicitly recited in Horrigan, a dimension was selected that was believed appropriate in view of the overall teachings of the Horrigan reference. The specific dimensions used in FEA were also consistent with physical prototypes used for testing.

7. The sheath model based upon the Horrigan teaching was constructed according to the Table attached hereto as Exhibit A. The sheath model was designed to have two layers of polymeric material. The inner layer of the model was TEFLON®[1] (PTFE), and the outer layer of the model was PEBAX®[2] (a polyether block amide copolymer).

8. In the braid-reinforced model, the braid was represented by a 16-strand annealed stainless steel[3] braid. Each strand has a wire diameter of 0.0762 mm. The braid wires made an angle of 55 degrees with the longitudinal axis. In practice, this angle can allow all the strands of the braid to be accommodated while winding. In the coil-reinforced model, the coil was represented by a rectangular spring tempered cross section steel flat wire. The flat wire had a width vs. thickness of 0.3028 mm vs. 0.1016 mm. The dimension of the

[1] Horrigan, Col. 3, line 54
[2] Horrigan, Col. 4, line 34
[3] Horrigan, Col. 4, line 23

coil wire was selected such that the cross-sectional area of the coil wire is substantially equivalent to the cross-sectional area of the 16-strand braid. The coil made an angle of 86 degrees with the longitudinal axis. Since the coil has only one wire, this large angle can be practically possible to achieve while winding. In the FEA models, a commonly-used smeared equivalent modeling approach was used to include the additional stiffness of the braid- and coil-reinforcements in the two-layer tubular model. This smearing helps to efficiently build and run the FEA models.

9. Following the construction of the computer FEA models, each sheath model was "bent" to a progressively larger bending angle. This action was intended to simulate the behavior of the sheath when exposed to bending of a type that may be encountered as the sheath traverses a tortuous passageway in the vasculature. A graphical depiction of the results of the bending simulation is provided in Exhibit B, attached hereto.

10. According to Exhibit B, the braid-reinforced sheath quickly began to lose its normalized diameter upon bending, and kinked at a bending angle of about 21 degrees. At this bending angle, the normalized stent diameter was reduced to about 0.6 and the circularity was about 60% of normal diameter. Upon further bending the braid-reinforced sheath lost its entire diameter at a bending angle of about 47 degrees.

11. At the bending angle of 21 degrees, the coil-reinforced sheath maintained a circularity of about 96%. This sheath maintained a normalized diameter of over 0.7 and circularity in excess of 70% of the original diameter until reaching a bending angle of 67 degrees.

12. According to the parameters utilized in my simulation, the coil-reinforced sheath was able to be bent to a much greater angle (67 degrees vs. 21 degrees) than the braid-reinforced sheath, while maintaining a normalized stent diameter greater than 70% of its original diameter.

13. It is desirable to maintain as large a normalized stent diameter as possible, so that the largest possible stent or other medical device can be passed through the sheath for deployment at a target site in the vasculature. As evidenced by the data in Exhibit B, between a bending angle of 21 degrees and 67 degrees, a much larger stent could be passed through a sheath constructed according to the coil model when compared to a sheath constructed according to the braid model.

Serial No. 08/725,936 Filed: October 7, 1996

I declare under penalty of perjury pursuant to the laws of the United States of America that the foregoing is true and correct, and that this Declaration was executed by me on April 23, 2007, at West Lafayette, Indiana.

Sathya Kaliyamoorthy

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Dimensions and Material Properties of the Sheath Designs

Variable	Data specified in Horrigan Patent	Picked value for FEA
Inner Layer (TEFLON)		
Elastic Modulus	-	460 MPa[1]
Inner Diameter	6Fr to 10Fr **Ref: Column 5; Line 1**	2.7178 mm (8 Fr)
Outer Diameter	Inner Diameter + 2*(Thickness =0.002 inch) **Ref: Column 4; Last but second line**	2.8194 mm
Outer Layer (PEBAX)		
Elastic Modulus	-	414 MPa[2]
Inner Diameter	Outer Diameter of Inner Layer	2.8194 mm
Outer Diameter	-	3.3020 mm
Braid Construction (16-strands)		
Wire Diameter	-	0.0762 mm
Angle with the longitudinal axis	-	55 Degrees
Elastic Modulus of the material of wire	Stainless Steel **Ref: Column 4; Second paragraph; Line 5**	200000 MPa
Coil Construction		
Width x Thickness	-	0.3048 mm x 0.1016 mm
Angle with the longitudinal axis	-	86 Degrees
Elastic Modulus of the material of coil	Stainless Steel	200000 MPa

[1]Typical value for TEFLON- Reference: DuPont **Teflon®** PTFE at Matweb
[2]Typical value for PEBAX- Reference: Arkema **Pebax®** 7033 at Matweb

EXHIBIT "A"

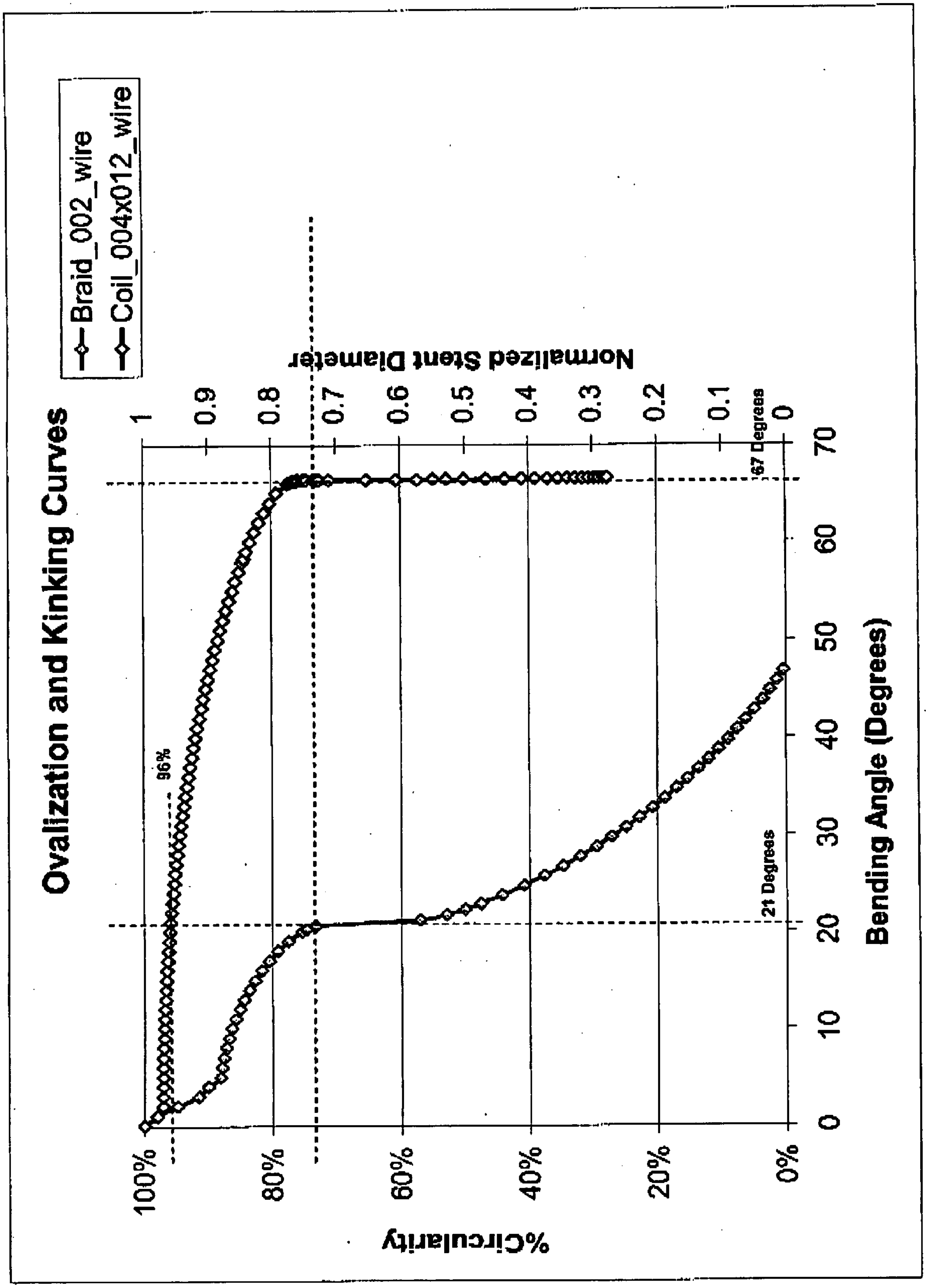
Ovalization and Kinking Curves
Braid_002_wire
Coil_004x012_wire
Normalized Stent Diameter
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
%Circularity
100%
80%
60%
40%
20%
0%
Bending Angle (Degrees)
0
10
20
30
40
50
60
70
96%
21 Degrees
67 Degrees

EXHIBIT "B"